

DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention

[30Day-22-0600]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Susceptibility testing" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 27, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Susceptibility testing (OMB Control No. 0920-0600, Exp. 2/20/2022) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting a Revision to approved information collection from participants in the CDC Model Performance for Mycobacterium tuberculosis Drug Susceptibility Testing for a period of three years. Revision of this information will not require changes in the scope of the project. This Revision includes (a) modification of the Instructions to Participants Letter; (b) modification of the MPEP Mycobacterium tuberculosis Results Worksheet; (c) modification of online data collection instrument; (d) modification of the MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration Results Worksheet; (e) removal of Reminder Telephone Script; and (f) modification of Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, corrections, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program (MPEP)

for Mycobacterium tuberculosis Susceptibility Testing is used to monitor and evaluate performance and practices among US laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing laboratories a self-assessment tool to test for drug resistant M. tuberculosis strains, the program aids laboratories in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards. Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) isolates. The PE isolates are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of drug susceptibility tests performed annually.

CDC is requesting OMB approval for an estimated 129 annual burden hours. Participation of respondents is voluntary, and there is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in
				hours)
Domestic Laboratory	Participant Biosafety Compliance Letter of Agreement	80	1	5/60
	MPEP Mycobacterium tuberculosis Results Worksheet	80	2	30/60
	Online Survey Instrument	80	2	15/60
	MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration Results Form	4	2	15/60

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